

Voluntary Recall of Filled Oxygen Tanks Skilled Nursing Facility Letter

Dear Oxygen Customer,

September 2, 2022

NorCal Respiratory Inc. is voluntarily recalling all oxygen tanks that were provided to your facility. The reason for this recall is that the filling of these tanks at NorCal Respiratory's facility did not meet the established federal requirements for current good manufacturing practice (CGMP) regulations, which are the adopted regulations in California. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The drug CGMP regulations help ensure that a product is safe for use, and that it has the ingredients and strength it claims to have. Additionally, the filling of the tanks with the Invacare Homefill® system was performed outside of the scope of the medical device manufacturer's specifications and beyond the approved use of the Homefill® system by the U.S. Food and Drug Administration (FDA). The filling of tanks using the Homefill® system is to be limited to the oxygen patient only, and the tanks must not be distributed to any other individual for any purpose, as per the warnings in the Invacare Homefill® Owner's and Operator Maintenance Manual.

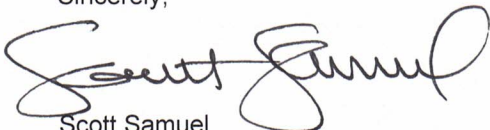
As an Invacare Homefill® oxygen system customer, it is likely that you were provided filled oxygen tanks from NorCal Respiratory Inc. from time to time, and on an as-needed basis, in order to accommodate the temporary needs of your facility's patients. These filled Homefill® system tanks were provided to meet the urgent needs of your patients and only to supplement your facility's ability to fill sufficient Homefill® tanks to meet your patients' needs.

If you still have any tanks that were filled with the original oxygen provided to you by NorCal Respiratory Inc., you are to contact NorCal Respiratory Inc. immediately at the number below, whereupon we will coordinate an exchange of that tank, or tanks, with other empty tank(s) that you can refill with the Homefill systems you have at your facility.

NorCal Respiratory phone: 530-246-1200

To be clear, there have been no reported adverse events associated with the practice of NorCal Respiratory providing filled oxygen tanks to patients or facilities from the Homefill® system. Nor are we aware of any issues or concerns associated with the safety or efficacy of the Homefill® system when operating it according to manufacturer's guidelines in a patient's home or a regulated facility. NorCal Respiratory Inc. is only performing this voluntary recall out of an abundance of caution and to fall in compliance with the requirements of the California Department of Health and the US FDA. We appreciate your business and apologize for any inconvenience that may be caused by this recall.

Sincerely,



Scott Samuel

VP of Compliance

Voluntary Recall of Filled Oxygen Tanks

Patient Letter

Dear Oxygen Customer,

September 2, 2022

NorCal Respiratory Inc. is voluntarily recalling all tanks that were filled with oxygen at the time of set up, whether or not the tanks may still contain oxygen. The reason for this recall is that the filling of these tanks at NorCal Respiratory's facilities did not meet the established federal requirements for current good manufacturing practice (CGMP) regulations, which are the adopted regulations in California. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The drug CGMP regulations help ensure that a product is safe for use, and that it has the ingredients and strength it claims to have. Additionally, the filling of tanks with the Invacare Homefill® system was performed outside of the scope of the medical device manufacturer's specifications and beyond the approved use of the Homefill® system by the US Food and Drug Administration (FDA). The filling of tanks using the Homefill® system is to be limited to the oxygen patient only, and the tanks must not be distributed to any other individual for any purpose, as per the warnings in the Homefill® Owner's and Operator Maintenance Manual.

Our records show that you were set up with the Invacare Homefill® system from NorCal Respiratory Inc. for your home oxygen needs. Because you were set up with this system, it is likely that you were provided a tank of oxygen at the time of setting up this Homefill® system in order to facilitate your transport to your home and/or provide oxygen until you were able to use the oxygen concentrator and/or fill the Homefill® tanks provided to you at your home.

If you still have a tank that was filled with the original oxygen provided to you by NorCal Respiratory Inc. on the day of your equipment set up, you are to contact NorCal Respiratory Inc. immediately at the number below, whereupon we will coordinate an exchange of that tank with an empty tank that you can refill with the Homefill system you have at your home.

NorCal Respiratory phone: 530-246-1200

To be clear, there have been no reported adverse events associated with the practice of NorCal Respiratory providing filled oxygen tanks to patients or facilities from the Homefill® system. Nor are we aware of any issues or concerns associated with the safety or efficacy of the Homefill® system when operating it according to manufacturer's guidelines in a patient's home. NorCal Respiratory Inc. is only performing this voluntary recall out of an abundance of caution and to fall in compliance with the requirements of the California Department of Health and the US FDA. We appreciate your business and apologize for any inconvenience that may be caused by this recall.

Sincerely,



Scott Samuel

VP of Compliance